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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,296	10/16/2003	John T. Kilcoyne	1065-012US03	7920
28863	7590	04/05/2007	EXAMINER	
SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			BAXTER, ZOE E	
			ART UNIT	PAPER NUMBER
			3735	
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE		DELIVERY MODE	
3 MONTHS	04/05/2007		PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,296	KILCOYNE ET AL.	
	Examiner	Art Unit	
	Zoe E. Baxter	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 10-16 and 55-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 10-16,55 and 59-67 is/are rejected.
- 7) Claim(s) 56-58 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 October 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/11/04, 8/1/06, 1/12/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

1. The drawings are objected to because letters, numbers and lines are not uniformly thick and well defined, clean, durable and black as specified by 37 CFR 1.84(i). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The substitute specification filed April 23, 2004 is acknowledged and is accepted into the record.
3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10, 11, 14-16, 55, 62 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Brockway et al. (US Patent No. 6409674 B1).

5. Referring to claim 10 Brockway et al. teach a monitoring device for monitoring at least one physiological parameter at an attachment site in a body, comprising: a housing, having a tissue attachment surface (column 8 lines 10-19); a securing structure which is movable from a retracted position to allow the

tissue attachment surface to be brought into contact with tissue at a preselected attachment site, and an extended position in which it extends through tissue in contact with the attachment surface (column 13 lines 35-53); and at least one physiological parameter detector carried by the housing (column 8 lines 10-19)..

6. Referring to claim 11 Brockway et al. teach a monitoring device comprising a concavity on the housing such that the tissue attachment surface is on a surface of the concavity (figure 3D reference 312D). It can be seen in the figure the barbs are attached to the housing in such a way that there is a concavity where the barbs attach to the tissue.

7. Referring to claim 14 Brockway et al. teach a monitoring device, wherein the physiological parameter detector comprises a pH detector (column 14 line 61-column 15 line 4).

8. Referring to claim 15 Brockway et al. teach a monitoring device comprising an RF transmitter (column 7 lines 41-55).

9. Referring to claim 16 Brockway et al. teach a monitoring device, comprising an electrical contact for contacting tissue in the body and transmitting data relating to the physiological parameter through the tissue (column 10 line 51-column 11 line 5).

10. Referring to claim 55 Brockway et al. teach a monitoring device wherein the securing structure comprises a pin (figure 3D reference number 312D).

11. Referring to claim 62 Brockway et al. teach a monitoring device, wherein the housing includes a docking structure that permits removable attachment of

the monitoring device to an introduction instrument that introduces the monitoring device to the preselected attachment site (column 11 line 65-column 12 line 10). Brockway et al. describe the docking structure as a catheter.

12. Referring to claim 63 Brockway et al. teach a monitoring device, wherein the docking structure comprises a projection, described as a plunger (column 12 lines 11-12), a lumen (figure 6 reference number 640), and a recess (column 12 lines 8-10) described as a cavity.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. as applied to claim 10 above, and further in view of Kohn et al. (US Patent No. 4638045). Brockway et al. fail to teach a monitoring device wherein the securing structure comprises a bioabsorbable material. Kohn et al. teach a bioabsorbable material and specifically the ability of sensors to be manufactured from the material (column 1 lines 6-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway et al. to include a bioabsorbable material similar to that of

Kohn et al. in order for the monitoring device to decompose harmlessly within a known period of time (Kohn et al. column 11 lines 25-37).

15. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. as applied to claim 11 above, and further in view of Makower et al. (US Patent No. 6190353 B1). Brockway et al. teaches a monitoring device comprising a lumen (figure 6 reference number 605) in communication with the concavity (figure 3D reference 312D). Brockway et al. fail to teach a monitoring device, comprising a lumen in communication with the concavity, for connection to a vacuum to draw tissue into the concavity. Makower et al. teach the use of a vacuum to draw tissue into a lumen (column 38 lines 1-7). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway et al. to include a vacuum device similar to that of Makower et al. in order to draw the tissue into the concavity (Makower et al. column 38 lines 1-7).

16. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. as applied to claim 10 above, and further in view of Bombeck, IV (US Patent No. 4981470). Brockway et al. fail to teach a monitoring device, wherein the preselected attachment site is an esophagus. Bombeck, IV teaches a pH sensor located on a catheter wherein the pH sensor remains in the esophagus (column 3 lines 21-29). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway et al. to be implantable within the esophagus similar to that of Bombeck, IV in to diagnose gastroesophageal reflux (column 2 lines 46-57).

17. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. as applied to claim 14 above, and further in view of Bombeck, IV (US Patent No. 4981470). Brockway et al. fail to teach a monitoring device, wherein the pH detector comprises an antimony electrode. Bombeck, IV teaches a pH sensor comprising an antimony electrode (column 4 lines 51-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway et al. to include an antimony electrode similar to that of Bombeck, IV in to diagnose gastroesophageal reflux (column 2 lines 46-57).

18. Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. in view of Makower et al. (US Patent No. 6190353 B1). Brockway et al. teaches a monitoring device for monitoring at least one physiological parameter at an attachment site in a body, comprising: a housing, having a tissue attachment surface (column 8 lines 10-19); a securing structure (column 13 lines 35-53), wherein the securing structure comprises a pin that is movable from a retracted position to allow the tissue attachment surface to be brought into contact with the tissue, and an extended position in which it extends through the tissue in contact with the attachment surface (column 13 lines 35-53); a concavity on the housing such that the tissue attachment surface is on a surface of the concavity (figure 3D reference 312D), it can be seen in the figure the barbs are attached to the housing in such a way that there is a concavity where the barbs attach to the tissue; and at least one physiological parameter detector carried by the housing (column 8 lines 10-19), Brockway et

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al. fail to teach a monitoring device, comprising a lumen in communication with the concavity, for connection to a vacuum to draw tissue into the concavity.

Makower et al. teach the use of a vacuum to draw tissue into a lumen (column 38 lines 1-7). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Brockway et al. to include a vacuum device similar to that of Makower et al. in order to draw the tissue into the concavity (Makower et al. column 38 lines 1-7).

19. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. in view of Makower et al., as applied to claim 65 above, and further in view of Kohn et al. (US Patent No. 4638045). Brockway et al. and Makower et al. fail to teach a monitoring device wherein the securing structure comprises a bioabsorbable material. Kohn et al. teach a bioabsorbable material and specifically the ability of sensors to be manufactured from the material (column 1 lines 6-12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Brockway et al. and Makower et al. to include a bioabsorbable material similar to that of Kohn et al. in order for the monitoring device to decompose harmlessly within a known period of time (Kohn et al. column 11 lines 25-37).

20. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. Brockway et al. do not expressly disclose monitoring device comprising a window, which permits visualization of the interior of the concavity through the housing.

21. At the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include a window in the device because Applicant has not disclosed that providing a window in the monitoring device provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore would have expected the monitoring device of Brockway et al. and the applicant's invention to perform equally well with either the monitor taught by Brockway et al. or the claimed monitoring device comprising a window because both monitors would perform the same function equally well.

22. Therefore, it would have been *prima facie* obvious to modify Brockway et al. to obtain the invention as specifies in claim 59 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Brockway et al.

23. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brockway et al. Brockway et al. do not expressly disclose monitoring device comprising a window comprising a transparent wall of the housing.

24. At the time of the invention, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include a window comprising a transparent wall of the housing in the device because Applicant has not disclosed that providing a window comprising a transparent wall of the housing in the monitoring device provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore would have expected the monitoring device of Brockway et al. and the applicant's

invention to perform equally well with either the monitor taught by Brockway et al. or the claimed monitoring device comprising a window comprising a transparent wall of the housing because both monitors would perform the same function equally well.

25. Therefore, it would have been *prima facie* obvious to modify Brockway et al. to obtain the invention as specified in claim 60 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Brockway et al.

Allowable Subject Matter

26. Claims 56-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Prior art of record fail to teach or fairly suggest a monitoring device as claimed by the Applicant wherein the securing structure extends part way across the concavity when in the extended position.

Conclusion

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zoe E. Baxter whose telephone number is 571-272-8964. The examiner can normally be reached on Monday-Friday 7:30am-4:00pm.

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28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charles A. Marmor, II
Supervisory Patent Examiner
Art Unit 3735

ZEB